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10/575,235	10/06/2006	Mauro Angeletti	2512-1178	6996
⁴⁶⁵ YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314			<div>EXAMINER</div> <div>CHEN, CATHERYNE</div>	
			<div>ART UNIT</div> <div>1655</div>	<div>PAPER NUMBER</div>
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/575,235

Applicant(s)

ANGELETTI ET AL.

Examiner

CATHERYNE CHEN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date April 7, 2006
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Currently, Claims 1-22 are pending. Claims 1-22 are examined on the merits.

Election/Restrictions

Applicant's election with traverse of the species XAD-4 in the reply filed on Nov. 29, 2007 is acknowledged. The traversal is on the ground(s) that there is not lack of special technical feature for the polystyrene resin. This is not found persuasive because the resins are structurally distinct because they bind different size molecules. Thus, there is a lack of special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 7, 8, 10, 11, 14, 15, 16, 18, 20 are objected to because of the following informalities:

Claim 7 requires a space after the letter "n" for "between30" and after the letter "d" for "and20."

Claim 8 has an extra period after the word "is."

Claims 10, 11 require a deletion of the space after the colon.

Claim 14 requires the word "claim" before the number "9." There should be no space between "non aqueous."

Claim 15 requires the word "claim" before the number "10."

Claim 16 requires a space after the letter "n" between the word "onpolystyrenic."

Claim 18 requires a space after the letter y for the word "anyother."

Claim 20 requires a deletion of space after the number "19" or before the comma.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, what is meant by "after the work up to which the grapes have been subjected?" How was the grape seeds treated before separation?

Regarding claim 2, "ex." which stands for the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In Claim 12, the term "low" percentage is indefinite because it is unclear what oxygen are considered "low" percentage.

In Claim 19, the term "high" polyphenol content and the term "low" content of monomeric substances are indefinite because it is unclear what polyphenol and monomerics are considered "high" and "low" content, respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-6, 9, 12, 14-15, 18-20, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Grape Seed Extract White Paper
(<http://www.activin.com/Testing%20White%20paper...html>).

Grape Seed Extract White Paper teaches the rich sources of proanthocyanidins in nature are grape seed from wine grapes (*Vitis vinifera*). Grape seed extracts are poor source of monomers, ranging from 1 to 30%, compared to green tea extracts, which contain significantly higher levels of more beneficial monomers at a much lower cost than do the grape seed extracts. Green tea extracts are not the best sources of OPCS (page 3, paragraph 1). Seeds used in the manufacture of grape seed extracts can be acquired from either grape juice operations or from wine producers after

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they have been discarded from the winemaking process (page 3, Seed Management, paragraphs 1 and 3). The most important aspect of seed management is the drying, separating and storage. Seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols. Several methods of drying are commonly used, including sun drying or mechanical drying using ovens or kilns. The seeds must be stored properly to prevent mildew or oxidation. Improperly stored seeds have been known to rapidly lose their potency and render them useless for extraction purposes. By removing excess moisture and minimizing their exposure to oxidizing elements, grape seeds can be stored for prolonged periods of time, while maintaining their OPC potency (page 4, paragraphs 2, 4-5). Extraction with water and ethanol, where the solvents are then recovered and the resulting concentrate is then either spray dried or vacuum dried and ground to final specifications (page 4, Seed Processing). Grape seed extract is qualitatively separated by thin layer chromatography (page 5, Methods of Analysis), HPLC (page 10), Gel permeation Chromatography (page 10).

Claims 1, 7, 9, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (CN 1363363 A).

Li et al teaches grape seed oil preparations by squeezing grape seed and treating the grape seed oil with 70% ethanol, where grapes are from *vitis vinifera*, as a functional food tablet, soft capsule, hard capsule or oral liquid (Abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-15, 17-20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grape Seed Extract White Paper (http://www.activin.com/Testing%20White%20paper_.html).

Grape Seed Extract White Paper teaches the rich sources of proanthocyanidins in nature are grape seed from wine grapes (*Vitis vinifera*). Grape seed extracts are poor sources of monomers, ranging from 1 to 30%, compared to green tea extracts, which contain significantly higher levels of more beneficial monomers at a much lower cost than do the grape seed extracts. Green tea extracts are not the best sources of OPCS (page 3, paragraph 1). Seeds used in the

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manufacture of grape seed extracts can be acquired from either grape juice operations or from wine producers after they have been discarded from the winemaking process (page 3, Seed Management, paragraphs 1 and 3). The most important aspect of seed management is the drying, separating and storage. Seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols. Several methods of drying are commonly used, including sun drying or mechanical drying using ovens or kilns. The seeds must be stored properly to prevent mildew or oxidation. Improperly stored seeds have been known to rapidly lose their potency and render them useless for extraction purposes. By removing excess moisture and minimizing their exposure to oxidizing elements, grape seeds can be stored for prolonged periods of time, while maintaining their OPC potency (page 4, paragraphs 2, 4-5). Extraction with water and ethanol, where the solvents are then recovered and the resulting concentrate is then either spray dried or vacuum dried and ground to final specifications (page 4, Seed Processing). Grape seed extract is qualitatively separated by thin layer chromatography (page 5, Methods of Analysis), HPLC (page 10), Gel permeation Chromatography (page 10). However it does not teach organic cultivation and the temperature, humidity, ethanol-water ratio, drug-liquor ratio, pressure.

The reference does not specifically teach performing the process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure claimed by applicant. The process in the temperature, humidity, ethanol-water ratio, drug-liquor

ratio and pressure is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Organic sources of grape seed would be an obvious substitute for grape seeds cultivated with herbicide and pesticide because grape seed extracts have been reported to prevent chemical and environmental pollutant toxicity (page 1, paragraph 2). Thus, an artisan of ordinary skill would reasonably expect that using organic source of grape seed could be used as the types grape seeds to prevent chemical and environmental pollutant toxicity taught by the reference. This reasonable expectation of success would motivate the artisan to use organic source of grape seed in the reference composition. Thus, using organic source of grape seed is considered an obvious modification of the reference.

Claims 1-3, 5-20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grape Seed Extract White Paper (http://www.activin.com/Testing%20White%20paper_.html) as applied to claims 1-3, 5-15, 17-20, 22 above, and further in view of Cuomo et al. (US 6358542 B2).

Grape Seed Extract White Paper teaches the rich sources of proanthocyanidins in nature are grape seed from wine grapes (*Vitis vinifera*). Grape seed extracts are poor sources of monomers, ranging from 1 to 30%, compared to green tea extracts, which contain significantly higher levels of more beneficial monomers at a much lower cost than do the grape seed extracts. Green tea extracts are not the best sources of OPCS (page 3, paragraph 1). Seeds used in the manufacture of grape seed extracts can be acquired from either grape juice operations or from wine producers after they have been discarded from the winemaking process (page 3, Seed Management, paragraphs 1 and 3). The most important aspect of seed management is the drying, separating and storage. Seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols. Several methods of drying are commonly used, including sun drying or mechanical drying using ovens or kilns. The seeds must be stored properly to prevent mildew or oxidation. Improperly stored seeds have been known to rapidly lose their potency and render them useless for extraction purposes. By removing excess moisture and minimizing their exposure to

oxidizing elements, grape seeds can be stored for prolonged periods of time, while maintaining their OPC potency (page 4, paragraphs 2, 4-5). Extraction with water and ethanol, where the solvents are then recovered and the resulting concentrate is then either spray dried or vacuum dried and ground to final specifications (page 4, Seed Processing). Grape seed extract is qualitatively separated by thin layer chromatography (page 5, Methods of Analysis), HPLC (page 10), Gel permeation Chromatography (page 10). However it does not teach organic cultivation and the temperature, humidity, ethanol-water ratio, drug-liquor ratio, pressure, XAD-4.

Cuomo et al. teaches solid matrix can be any material having a stronger affinity for at least some of the antioxidant components than for the aqueous phase. The solid matrix material is a polymeric adsorbent material resin of Amberlite XAD-4 (column 7, lines 47-67).

Grape Seed Extract White Paper teaches method to extract proanthocyanidins, which are antioxidative elements (page 1, paragraph 1). Cuomo et al. teaches XAD-4 can be used to purify antioxidants (see discussion above). Thus, it would be obvious to use XAD-4 to isolate antioxidants, such as that taught by grape seed extracts. An artisan of ordinary skill would clearly expect that the XAD-4 taught by Cuomo et al. would function successfully to isolate the antioxidant taught by Grape Seed Extract White Paper. This reasonable expectation of success would motivate the artisan to modify the method of grape seed extraction to include a XAD-4 column as an effective means to extract the grape seed extract.

The reference does not specifically teach performing the process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure claimed by applicant. The process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Organic sources of grape seed would be an obvious substitute for grape seeds cultivated with herbicide and pesticide because grape seed extracts have been reported to prevent chemical and environmental pollutant toxicity (page 1, paragraph 2). Thus, an artisan of ordinary skill would reasonably expect that using organic source of grape seed could be used as the types grape seeds to prevent chemical and environmental pollutant toxicity taught by the reference. This reasonable expectation of success would motivate the artisan to use organic source of grape seed in the reference composition.

Thus, using organic source of grape seed is considered an obvious modification of the reference.

Claims 1-20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grape Seed Extract White Paper (<http://www.activin.com/Testing%20White%20paper.html>) and Cuomo et al. (US 6358542 B2) as applied to claims 1-3, 5-20, 22 above, and further in view of Schulman et al. (US 4609110).

Grape Seed Extract White Paper teaches the rich sources of proanthocyanidins in nature are grape seed from wine grapes (*Vitis vinifera*). Grape seed extracts are poor sources of monomers, ranging from 1 to 30%, compared to green tea extracts, which contain significantly higher levels of more beneficial monomers at a much lower cost than do the grape seed extracts. Green tea extracts are not the best sources of OPCS (page 3, paragraph 1). Seeds used in the manufacture of grape seed extracts can be acquired from either grape juice operations or from wine producers after they have been discarded from the winemaking process (page 3, Seed Management, paragraphs 1 and 3). The most important aspect of seed management is the drying, separating and storage. Seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols. Several methods of drying are commonly used, including sun drying or mechanical drying using ovens or kilns.

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The seeds must be stored properly to prevent mildew or oxidation. Improperly stored seeds have been known to rapidly lose their potency and render them useless for extraction purposes. By removing excess moisture and minimizing their exposure to oxidizing elements, grape seeds can be stored for prolonged periods of time, while maintaining their OPC potency (page 4, paragraphs 2, 4-5). Extraction with water and ethanol, where the solvents are then recovered and the resulting concentrate is then either spray dried or vacuum dried and ground to final specifications (page 4, Seed Processing). Grape seed extract is qualitatively separated by thin layer chromatography (page 5, Methods of Analysis), HPLC (page 10), Gel permeation Chromatography (page 10). However it does not teach organic cultivation and the temperature, humidity, ethanol-water ratio, drug-liquor ratio, pressure, XAD-4, the seed separator.

Cuomo et al. teaches solid matrix can be any material having a stronger affinity for at least some of the antioxidant components than for the aqueous phase. The solid matrix material is a polymeric adsorbent material resin of Amberlite XAD-4 (column 7, lines 47-67).

Schulman et al. teaches an apparatus to provide for separation of seed particles (column 4, lines 44-55), where the spacing between the gap may be regulated in correlation with the type of fruit for effective seed separation, such as grapes (column 6, lines 36-41). Thus, an artisan of ordinary skill would reasonably expect that isolating grape seeds be a seed separator could be used as the types of method to separate seeds from grapes in order to extract antioxidants from grape seed as taught by the

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references (see discussion above). This reasonable expectation of success would motivate the artisan to use a seed separator in the reference method. Thus, using a seed separator to isolate grape seeds is considered an obvious modification of the references.

Grape Seed Extract White Paper teaches method to extract proanthocyanidins, which are antioxidative elements (page 1, paragraph 1). Cuomo et al. teaches XAD-4 can be used to purify antioxidants (see discussion above). Thus, it would be obvious to use XAD-4 to isolate antioxidants, such as that taught by grape seed extracts. An artisan of ordinary skill would clearly expect that the XAD-4 taught by Cuomo et al. would function successfully to isolate the antioxidant taught by Grape Seed Extract White Paper. This reasonable expectation of success would motivate the artisan to modify the method of grape seed extraction to include a XAD-4 column as an effective means to extract the grape seed extract.

The reference does not specifically teach performing the process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure claimed by applicant. The process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary

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for an artisan of ordinary skill to determine the optimal process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Organic sources of grape seed would be an obvious substitute for grape seeds cultivated with herbicide and pesticide because grape seed extracts have been reported to prevent chemical and environmental pollutant toxicity (page 1, paragraph 2). Thus, an artisan of ordinary skill would reasonably expect that using organic source of grape seed could be used as the types grape seeds to prevent chemical and environmental pollutant toxicity taught by the reference. This reasonable expectation of success would motivate the artisan to use organic source of grape seed in the reference composition. Thus, using organic source of grape seed is considered an obvious modification of the reference.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/

Primary Examiner, Art Unit 1655